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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,773	10/09/2001	Yutaka Kanda	249-202	2525

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EXAMINER	
LI, QIAN J	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/971,773	KANDA ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

I. Claims 1-3 and 20 are drawn to a CHO cell into which a gene encoding an antibody molecule is introduced, and a method of using such cell for antibody production . Classified in class 435, subclass 69.1, and 455.

II. Claims 1, 4-19, and 23-40 are drawn to a cell in which the activity of an enzyme relating to the synthesis of an intracellular nucleotide GDP-fucose and/or relating to the modification of a sugar chain is decreased or deleted, and a method of using such cell for antibody production. Classified in class 435, subclass 69.1, and 455.

III. Claims 21, 22, 41, 54-56 are drawn to antibodies. Classified in class 530, subclass 387.1.

IV. Claims 42-50 are drawn to transgenic non-human animal comprising a genome modified such that the activity of an enzyme relating to the synthesis of an intracellular sugar nucleotide GDP-fucose and/or relating to the modification of a sugar chain is decreased, wherein the enzyme is GMD. Classified in class 800, subclass 13.

V. Claims 42-50 are drawn to transgenic non-human animal comprising a genome modified such that the activity of an enzyme relating to the synthesis of an intracellular sugar nucleotide GDP-fucose and/or relating to the modification of

a sugar chain is decreased, wherein the enzyme is Fx. Classified in class 800, subclass 13.

VI. Claims 42-50 are drawn to transgenic non-human animal comprising a genome modified such that the activity of an enzyme relating to the synthesis of an intracellular sugar nucleotide GDP-fucose and/or relating to the modification of a sugar chain is decreased, wherein the enzyme is GFPP. Classified in class 800, subclass 13.

VII. Claims 42-50 are drawn to transgenic plant comprising a genome modified such that the activity of an enzyme relating to the synthesis of an intracellular sugar nucleotide GDP-fucose and/or relating to the modification of a sugar chain is decreased, wherein the enzyme is GMD. Classified in class 435, subclass 419.

VIII. Claims 42-50 are drawn to transgenic plant comprising a genome modified such that the activity of an enzyme relating to the synthesis of an intracellular sugar nucleotide GDP-fucose and/or relating to the modification of a sugar chain is decreased, wherein the enzyme is Fx. Classified in class 435, subclass 419.

IX. Claims 42-50 are drawn to transgenic plant comprising a genome modified such that the activity of an enzyme relating to the synthesis of an intracellular sugar nucleotide GDP-fucose and/or relating to the modification of a sugar chain is decreased, wherein the enzyme is GFPP. Classified in class 435, subclass 419.

X. Claims 51-53 are drawn to a method for producing an antibody using a transgenic animal. Classified in class 800, subclass 6.

XI. Claims 51-53 are drawn to a method for producing an antibody using a transgenic plant. Classified in class 800, subclass 288.

XII-XVI. Claims 57 and 58 are drawn to a polypeptide, each of the group XII-XVI is drawn to a specific amino acid sequence selected from the group consisting of SEQ ID Nos: 23, 24, 71, 72, 73. Classified in class 530, subclass 350.

XVII-XXIV. Claims 59-61 are drawn to a polynucleotide, each of the group XVII-XXIV is drawn to a specific polynucleotide sequence selected from the group consisting of SEQ ID Nos: 1-3, 48, 51, 65, 67, and 70. Classified in class 536, subclass 23.1.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II-IX, XII-XXIV, and I are independent and distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are drawn to distinct products, e.g. polynucleotides, polypeptides, transgenic plants, transgenic animals and antibodies. Different products have distinct structure and belong to different chemical entities. For example, the CHO cells of group I have a normal activity of an enzyme relating to the synthesis of an intracellular nucleotide GDP-fucose

and/or relating to the modification of a sugar chain, whereas the activity of such enzyme is decreased or deleted in the CHO cells of group II. The animal or plant of groups IV-IX are distinct because each comprises different enzymes relating to the synthesis of an intracellular nucleotide GDP-fucose and/or relating to the modification of a sugar chain, wherein the activity of the enzyme is decreased or deleted, which is made possible by genome modification, and thus, each would have a distinct genotype and phenotype. Each of the groups XII-XXIV is drawn to a distinct polynucleotide or polypeptide sequence.

Inventions II, X, XI, and I are independent and distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are drawn to different methods of making an antibody. The distinct methods use different starting materials, have different method steps, different modes of operation, and have distinct technical considerations. For example, the transgenic animal would not be used in the method of group XI, and the CHO cells having reduced or deleted enzymes are not required for cells used in the method of group I.

Inventions X and IV-VI, and XI and VII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the

method of group X or XI could be practiced with a different animal (such as recited in groups IV-VI), or a different transgenic plant (such as recited in groups VII-IX), and the product as claimed could be used for processes other than producing an antibody, such as drug testing.

The differences of the Inventions I-XXIV are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

Invention group II is directed to a combination of distinct species of cells comprising distinct species of enzymes, whose activity relating to the synthesis of an intracellular nucleotide GDP-fucose and/or relating to the modification of a sugar chain is decreased or deleted, which is caused by different ways of manipulation. If invention group II is elected, further election of a species, drawn to a specific combination is necessary, i.e. elect a specific cell as recited in claim 36, comprising a specific defective enzyme as recited in claim 5, made by a specific method as recited in claim 15. Currently all claims of group II are generic, i.e. no single claim is drawn to a specific combination.

Invention group III is drawn to structurally different antibodies. If invention group III is elected, further election of a species drawn to a specific antibody is necessary. Currently, all claims of group III is generic.

Invention groups X and XI are drawn to methods of using different transgenic animal or plants. If one of the invention groups X and XI is elected, further election of a species, drawn to using a specific starting material, is necessary. Currently all claims of groups X and XI are generic, i.e. no single claim is drawn to a specific starting material.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 9:30 am - 6 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
June 16, 2003